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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,229	06/25/2001	Richard Ian Christopherson	DAVI139.001A	2287

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EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicati n N .</b>	<b>Applicant(s)</b>	
	09/869,229	CHRISTOPHERSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cheyne D Ly	1631	

**-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 58-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/12/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicants' arguments filed October 12, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The cancellation of claims 1-57 and addition of claims 58-71 have been acknowledged.
3. Claims 58-71 are examined on the merits.

### **CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 58-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. NEW MATTER.
6. This rejection is necessitated by Applicants amendments.
7. Specific to claim 58, lines 8-9, the limitation of "establishes concurrently a discriminatory image of antigen expression" has not been found in the instant specification. It is noted that the pointed to support (page 47, lines 15-23) provides disclosure for "Images are captured and analyzed" which is different from the new limitation of "establishes

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concurrently a discriminatory image of antigen expression". The same issue is present in claims 59, 62, 63, and 65.

8. Claim 71, lines 3-4, recites the limitation of "bound to protein G that is first coated on the solid support" which has not been found in the instant specification. It is noted that the specification discloses "the array is initially coated with a recombinant, truncated form of protein G" which is different from the limitation of "protein G."

### **CLAIM REJECTIONS - 35 USC § 102**

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 58-70 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yoshinari et al. (1996).

11. This rejection is necessitated by Applicants amendments.

### **RESPONSE TO ARGUMENTS**

12. Applicant's arguments (pages 6-13) have been considered and found to be unpersuasive because said arguments are directed to cancelled claims.

13. Yoshinari et al. describes an ELISA device comprising an array of the four MAbs selected from the screening with A549 lung adenocarcinoma cells in 96-well microplates (immobilized in discrete regions) wherein said MAbs react to different surface antigens. The two controls show no reactivity to the cells (page 363, column 1, Results §). Yoshinari et al. supports that the MAbs bind to different surface antigens by performing antigen

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immunoblotting wherein MAbs 28K29 and ZLG40 reacted with bands of approximately 600,000 and 50,000, respectively. The Mab 2938 bound to one or more substances more than 1,000,000 (page 364, column 2, to page 365, column 1, Antigen Immunoblotting §), claims 58-60 and 62-70.

14. The assay device of Yoshinari et al. detects surface antigens from myeloma cell line (page 359, column 2, last paragraph), as in instant claim 61.

15. It is noted that claims 58-70 are directed to an assay device with the intended use of determining the presence of cancer or a disease. For example, claim 1, lines 1-2, recites the intended use as further supported by the lines 7-12 starting with the phrase “wherein”. The MPEP states that the intended use in an apparatus claim does not distinguish over the prior art apparatus. If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See MPEP 2111.02 [R-2]. The limitations have reasonably construed, as the intended use of the claimed assay device, therefore, does not distinguish said device over the prior art cited above. Further, line 6 recites the limitation of “capable of interacting” and lines 7-12 recites “wherein...establishes concurrently a discriminatory image...” It is noted that the claim device does not have any limitations for generating “image of antigen expression.” The prior art device cited above has been reasonably construed as “capable of interacting” for establishing currently a discriminatory image.

### **CLAIM REJECTIONS - 35 USC § 103**

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 58-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshinari et al. (1996) in view of Pestronk et al. (1997).

19. This rejection is necessitated by Applicants amendments.

20. Yoshinari et al. describes the limitations to claims 58-70 as discussed above. However, Yoshinari et al. does not describe the limitations of claim 71.

21. Pestronk et al. describes an ELISA device with covalent linkage of GM1 to ELISA plates wherein IgM ant-GM1 binds to GM1 (Abstract etc.), as in instant claim 71. It is noted that the limitation of "bound to the array covalently" does not require that the immunoglobins to be directly "bound to the array covalently".

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22. Yoshinari et al. describes an improvement for generating antibodies by overcoming the difficulties of immobilization on glass slides by using a cells ELISA (page 359, column 1, 1<sup>st</sup> paragraph, and page 360, column 2, last paragraph).

23. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement described by Yoshinari et al. to improve on the device of Yoshinari et al. by using the ELISA with covalent linkage. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the assay device of Yoshinari et al. and Pestronk et al.

### **CONCLUSION**

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

25. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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27. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.


28. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly

1/8/05



MICHAEL P. WOODWARD  
SUPERVISORY PATENT EXAMINER  
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JAN 09 2005